Organovo Provides Timing for Release of FXR314 Phase 2 NASH Results

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SAN DIEGO, Dec. 06, 2023 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ: ONVO), a clinical stage biotechnology company that is focused on developing FXR314 in ulcerative colitis and inflammatory bowel disease (IBD), based on demonstration of clinical promise in three-dimensional (3D) human tissues as well as strong preclinical data, today announced that it will release final and complete data from a Phase 2a trial of FXR314 in non-alcoholic steatohepatitis (NASH) patients by April 2024. The Company anticipates presentations at scientific meetings as well as publication in peer-reviewed journals. The release of this data will be the first public release of the completed clinical trial data.

“We are enthusiastic about the opportunity for FXR314 to benefit patients with liver fibrosis, including in NASH and primary biliary cholangitis,” said Keith Murphy, Organovo executive chairman. “We believe it to be a best-in-class FXR agonist with significant differentiation due to its high potency and demonstrated safety, including much lower pruritus rates in relevant populations than comparator drugs. We look forward to releasing full FXR314 NASH results at scientific meetings and in a peer-reviewed journal.”

In an already reported interim analysis of about 60 patients after 16 weeks of treatment, FXR314 lowered liver fat content as demonstrated by a reduction in the median MRI-PDFF score of 28.6% in the 3 mg cohort and 26.9% in the 6 mg group compared with a reduction of only 1.5% in the placebo group. Post-hoc comparative assessment of relative liver fat reduction in the interim cohort found the decrease with 3 mg to be statistically significant compared to placebo (p=0.006). In a measure of activity in individual patients, FXR314 achieved greater than 30 percent liver fat reduction in 47 percent of patients (8/17) in the 3 mg cohort and 35 percent (6/17) in the 6 mg cohort, compared with 12 percent (2/17) in the placebo arm.

FXR314 was generally well-tolerated in this NASH population, with no treatment-related serious adverse events (AEs). All treatment-related AEs were mild-moderate with no apparent dose relationship. Mild-moderate pruritus was reported in one patient in the 3 mg cohort and one patient in the 6 mg cohort. No pruritus-related treatment discontinuations occurred.

Organovo’s current development program for FXR314 focuses on inflammatory bowel disease, where the drug’s differentiated mechanism of action, as highlighted in Organovo’s recently provided mechanism of action video at https://organovo.com/about/, provides substantial promise that the drug’s impact will strongly complement the biology of other successful drugs in ulcerative colitis and Crohn’s disease. Organovo plans to begin enrollment for a proof-of-concept Phase 2 ulcerative colitis study in 1H 2024, with targeted completion in 1H 2025. The drug’s additional promise in liver fibrosis and NASH makes it a strong candidate for development in that area through partnership collaborations with Organovo.

About Organovo

Organovo is a clinical stage biotechnology company that is developing drugs that are demonstrated to be effective in three-dimensional (3D) human tissues as candidates for drug development. The company’s lead molecule, FXR314, is on the path for Phase 2 investigation in inflammatory bowel disease and has potential application in metabolic liver disease and oncology. The company has proprietary technology used to build 3D human tissues that mimic key aspects of native human tissue composition, architecture, function and disease. For more information visit Organovo's website at www.organovo.com.

Forward Looking Statements

Any statements contained in this press release that do not describe historical facts constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and uncertainties. These risks and uncertainties and other factors are identified and described in more detail in the Company’s filings with the SEC, including its Annual Report on Form 10-K filed with the SEC on July 14, 2023, as such risk factors are updated in its most recently filed Quarterly Report on Form 10-Q filed with the SEC on November 9, 2023. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that the Company may issue in the future. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

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